

REMARKS

I. Claims in the Case

Claims 2 and 22 have been amended and are now directed to oleandrin as one of the at least one digitalis glycosides. Claim 13 has been amended slightly to clarify that is reference additional glycosides that can be employed. Claim 21 has been amended to clarify the range. Claim 25 has been amended to clarify that the proliferative disease is a tumor. Claims 1 and 14-19 have been canceled. Claims 1-12 and 20-30 are pending.

II. Rejection of Claims 1, 13, 16, 22 and 24 as anticipated by Jones

The Action first rejects claims 1, 13, 16, 22 and 24 as anticipated by the Jones patent.

In response, Applicants have introduced the subject matter of dependent claim 14 into claim 1 and 22. As claim 14 was not included in this rejection, it is believed that such amendment obviates the rejection.

III. Rejection of Claims 1-3, 7, 13, 20, 22 and 24 as anticipated by Pitha

The Action first rejects claims 1-3, 7, 13, 20, 22 and 24 as anticipated by the Pitha patent.

In response, Applicants have introduced the subject matter of dependent claim 14 into claim 1 and 22. As claim 14 was not included in this rejection, it is believed that such amendment obviates the rejection.

IV. Rejection of Claims 1, 13-19, 21, 22 and 24-30 as Obvious over Jones in view of Michaels and Conrad *et al.*

The Action next rejects claims 1, 13-19, 21, 22 and 24-30 as obvious over Jones in view of Micheals and Conrad *et al.*

With respect to the rejection of the composition claims, it is noted that claim 2 was not rejected over this series of references, and thus since claim 2 has been placed into independent form, this should render at least claims dependent claims 13 and 21 patentable. Furthermore,

composition claim 22 has been amended to incorporate the “amorphous” and “oleandrin” elements of claim 2, which should render claims 22 and 24 patentable.

Additionally, with respect to claims 25-30, these claims are now depend from non-rejected claim 2 and thus should be clearly distinguished from the cited prior art, in that claim 2 was not rejected on this basis. Additionally, these claims now recite cancer therapy, a form of proliferative cell disease clearly distinct from congestive heart failure of Conrad.

V. Rejection of Claims 1, 13-19 and 21-30 as Obvious over Jones in view of Micheals and further in view of Rubinfeld

The Action next rejects claims 1, 13-19 and 21-30 as obvious over Jones in view of Micheals and further in view of Rubinfeld.

We first note that claim 2 was not rejected on this basis. Since all of the rejected claims now depend from claim 2 (or incorporate the “amorphous” and “oleandrin” limitations of claim 2), then each of these claims should now be free of the art with respect to this rejection.

VI. Rejection of Claims 1-7, 13, 16, 21, 22 and 24 as Obvious over Jones and Pitha

The Action next rejects claims 1-7, 13, 16, 21, 22 and 24 as obvious over Jones and Pitha.

In response, it is noted that previous claim 14 (“oleandrin”) was not rejected on the basis of these references. Thus, since all the claims are now directed to oleandrin, it is believed that this rejection is now overcome.

VII. Rejection of Claims 1-11, 13, 16, 21, 22 and 24 as obvious over Jones and Pitha further in view of Stella *et al.*

The Action next rejects claims 1-11, 13, 16, 21, 22 and 24 as obvious over Jones and Pitha and further in view of Stella *et al.*

In response, it is noted that previous claim 14 (“oleandrin”) was not rejected on the basis of these references. Thus, since all the claims are now directed to oleandrin, it is believed that this rejection is now overcome.

VIII. Rejection of Claims 1-3, 5-8, 13-22 and 24-30 over Braude *et al.* and Pitha

The Action next rejects claims 1-3, 5-8, 13-22 and 24-30 as obvious over the combination of Braude *et al.* and Pitha.

In response, Applicants have studied Braude *et al.* and note that it lists a large number of cardiac glycosides, and includes a mention of oleandrin, but we fail to see where it indicates that oleandrin has a solubility problem that needs to be addressed. If we have missed something in this regard, the Examiner is respectfully request that this be pointed out.

Similarly, we have reviewed the Pitha disclosure and have been unable to identify any teaching or suggestion with respect to oleandrin. Indeed, while two cardiac glycosides family members are specifically mentioned, we have been unable to identify any teaching relevant to the “family” in general or “oleandrin” in particular.

The foregoing being said, we would posit that the present claims now define subject matter that is patentably distinct from these references, alone or in combination. The basis for this proposition is that the claims are now very specifically directed to a specific combination, and there is no basis on this record – in either of the references now relied upon – for selecting oleandrin as being in need of combining with amorphous cyclodextrin.

Accordingly, the Examiner is requested to reconsider and withdraw this basis of rejection.

IX. Rejection of Claims 1-3, 5-8, 12-22 and 24-30 as Obvious Over a Series of References

Lastly, the Action rejects claims 1-3, 5-8, 12-22 and 24-30 as obvious over a combination of Braude et al. and Pitha, further in view of a broad series of tertiary references.

It appears that this rejection is entered merely to address the patentability of claim 12, directed various polysaccharides.

With respect to Braude *et al.* and Pitha, Applicants incorporate the arguments in the immediately preceding section.

With respect to the tertiary references, Applicants are unable to identify any teachings there relevant to oleandrin/cyclodextrin combinations and their use in cancer treatment. If the Applicants have missed some relevant teaching in this regard, the Examiner is respectfully requested to identify the teaching relied upon.

X. Conclusion

The Examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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